AMENDMENTS TO THE CLAIMS

1-76. (cancelled).

77. (currently amended) A method for preparing a sterile pharmaceutical composition of a steroid comprising:
(i) dissolving a non-sterile steroid in a non-aqueous solvent to yield a solution of the steroid,
(ii) filtering the solution of (i) to yield a sterile solution,
(iii) combining the sterile solution of (ii) with sterile water to form a sterile ~~an~~ aqueous suspension,
~~(iv) optionally removing all or part of the non-aqueous solvent from the aqueous suspension of (iii),~~
~~(v)~~ (iv) treating the sterile aqueous suspension of (iii) ~~or (iv)~~ to obtain a sterile ~~an~~ aqueous suspension with a particle size distribution having a mass median diameter less than 10 μm,
~~(vi)~~ (v) under sterile conditions combining the sterile aqueous suspension of ~~(v)~~ (iv) with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising a sterile ~~an~~ aqueous suspension of the steroid having a mass median diameter less than 10 μm, and
~~(vii)~~ (vi) storing the sterile pharmaceutical composition of ~~(vi)~~ (v) in sterile containers.

78. (previously presented) The method of claim 77, wherein the non-sterile steroid is a powder.

79. (previously presented) The method of claim 78, wherein the powder is a micronized powder.

80. (previously presented) The method of claim 77, wherein the steroid is budesonide.

81. (cancelled).

82. (previously presented) The method of claim 77, wherein the solvent comprises an alcohol.

83. (previously presented) The method of claim 77, wherein the solvent comprises a Class 3 solvent.

84. (previously presented) The method of claim 77, wherein the solvent comprises a Class 2 solvent.

85. (previously presented) The method of claim 77, comprising combining solvent with the steroid at a temperature from 20°C below the boiling point of the solvent up to its boiling point.

86. (previously presented) The method of claim 85, wherein the solvent is at reflux.

87. (previously presented) The method of claim 77, comprising removing solvent under reduced pressure.

88. (previously presented) The method of claim 77, comprising removing solvent at atmospheric pressure.

89. (previously presented) The method of claim 77, comprising filtering the solution through a filter having a pore size of 0.2 μm or less.

90. (previously presented) The method of claim 77, wherein the sterile water contains a surfactant.

91. (previously presented) The method of claim 77, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μm.

92. (previously presented) The method of claim 91, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μm.

93. (previously presented) The method of claim 77, comprising storing the sterile composition in sterile ampoules.

94. (currently amended) A method for preparing a sterile suspension of budesonide, comprising:
(i) dissolving non-sterile budesonide in a non-aqueous solvent to yield a budesonide solution,

(ii) filtering the solution of (i) to yield a sterile solution,
(iii) combining the sterile solution of (ii) with sterile water to form a sterile ~~an~~ aqueous suspension of budesonide,
~~(iv) optionally removing all or part of the non-aqueous solvent from the aqueous suspension of (iii),~~
~~(v)~~ (iv) treating the sterile aqueous suspension of (iii) ~~or (iv)~~ to obtain a sterile ~~an~~ aqueous suspension with a particle size distribution having a mass median diameter less than 10 μm,
~~(vi)~~ (v) under sterile conditions combining the sterile aqueous suspension of ~~(v)~~ (iv) with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising the sterile aqueous suspension of budesonide having a mass median diameter less than 10 μm, and
~~(vii)~~ (vi) storing the sterile pharmaceutical composition of ~~(vi)~~ (v) in sterile containers.

95. (previously presented) The method of claim 94, wherein the solvent comprises an alcohol.

96. (previously presented) The method of claim 94, comprising filtering the solution through a filter having a pore size of 0.2 μm or less.

97. (previously presented) The method of claim 96, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μm.

98. (previously presented) The method of claim 96, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μm.

99-106. (cancelled).

107. (new) A method for preparing a sterile pharmaceutical composition of a steroid comprising:
(i) dissolving a non-sterile steroid in a non-aqueous solvent to yield a solution of the steroid,
(ii) filtering the solution of (i) to yield a sterile solution,
(iii) combining the sterile solution of (ii) with sterile water to form a sterile aqueous suspension,
(iv) removing all or part of the non-aqueous solvent from the sterile aqueous suspension

of (iii) to yield a sterile aqueous suspension having reduced non-aqueous solvent content,

(v) treating the sterile aqueous suspension having reduced non-aqueous solvent content of (iv) to obtain a sterile aqueous suspension with a particle size distribution having a mass median diameter less than 10 μm,

(vi) under sterile conditions combining the sterile aqueous suspension of (v) with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising a sterile aqueous suspension of the steroid having a mass median diameter less than 10 μm, and

(vii) storing the sterile pharmaceutical composition of (vi) in sterile containers.

108. (new) A method for preparing a sterile pharmaceutical composition of budesonide comprising:

(i) dissolving a non-sterile budesonide in a non-aqueous solvent to yield a budesonide solution,

(ii) filtering the solution of (i) to yield a sterile solution,

(iii) combining the sterile solution of (ii) with sterile water to form a sterile aqueous suspension of budesonide,

(iv) removing all or part of the non-aqueous solvent from the sterile aqueous suspension of (iii) to yield a sterile aqueous suspension having reduced non-aqueous solvent content,

(v) treating the sterile aqueous suspension having reduced non-aqueous solvent content of (iv) to obtain a sterile aqueous suspension with a particle size distribution having a mass median diameter less than 10 μm,

(vi) under sterile conditions combining the sterile aqueous suspension of (v) with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising a sterile aqueous suspension of budesonide having a mass median diameter less than 10 μm, and

(vii) storing the sterile pharmaceutical composition of (vi) in sterile containers.

109. (new) The method of claim 94, comprising storing the sterile composition in sterile ampoules.

110. (new) The method of claim 107, comprising storing the sterile composition in sterile ampoules.

111. (new) The method of claim 108, comprising storing the sterile composition in sterile ampoules.